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Bonutti Research, Inc.
Unity Beta Anchor System
510(k) Premarket Notification

OCT 30 2008

510(k) SUMMARY

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367
Effingham, Illinois 62401
Phone: (217) 342-3412, ext. 321
Fax: (217) 342-1043

Date Prepared: September 29, 2008

Proprietary Name: Unity Beta Anchor System

Common Name: Fixation Device

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue.

Device Description: The Unity Beta Anchor System is designed for the fixation of tissue, ligament, tendon, and bone. Absorbable poly-L-lactic acid (PLLA) implant materials are ultrasonically joined to secure tissue, ligament, tendon, and bone at a repair site. An electrical generator provides ultrasonic energy to the end effector of a handpiece to weld the two pieces of implant material together and secure tissue, ligament, tendon, and/or bone. The system provides a means of sutureless fixation that facilitates overall suture management.

Indications for Use: The Unity Beta Anchor System consists of single patient use absorbable (PLLA) implants intended for use as fasteners (anchors) in the fixation of tissue, ligament, tendon, and bone. The system is indicated in general soft tissue approximation/ligation.

Predicate Device(s): Unity Beta Anchor System is similar in design and intended use to existing Bonutti Research, Inc., fixation products and various other suture anchors determined to be substantially equivalent and that are commonly used in tissue and bone fixation.

Predicate Comparison: Design verification testing identified and conducted as part of the risk analysis assessment compared the mechanical strengths and failure modes of the Unity Beta Anchor System to predicate devices.

Submitted by:

Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bonutti Research, Inc.,
% Mr. Patrick Balsmann, MBA, MS, RAC
Director, Regulatory/Clinical Affairs & QA
P.O. Box 1367
Effingham, Ilinois 62401

OCT 3 0 2008

Re K082906
Trade/Device Name: Unity Beta Anchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 29, 2008
Received: September 30, 2008

Dear Mr. Balsmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BONUTTI TECHNOLOGIES
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Indications for Use

510(k) Number: K082906

Device Name: Unity Beta Anchor System

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Prescription Use X AND/OR Over-The-Counter Use No
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082906